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The impact of introducing new vaccines on the health system: Case studies from six low- and middle-income countries

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ABSTRACT

Objective: We aimed to explore the impacts of new vaccine introductions on immunization programmes and health systems in low- and middle-income countries.
Methods: We conducted case studies of seven vaccine introductions in six countries (Cameroon, PCV; Ethiopia, PCV; Guatemala, rotavirus; Kenya, PCV; Mali, Meningitis A; Mali, PCV; Rwanda, HPV). Interviews were conducted with 261 national, regional and district key informants and questionnaires were completed with staff from 196 health facilities. Routine data from districts and health facilities were gathered on vaccination and antenatal service use. Data collection and analysis were structured around the World Health Organisation health system building blocks.
Findings: The new vaccines were viewed positively and seemed to integrate well into existing health systems. The introductions were found to have had no impact on many elements within the building blocks framework. Despite many key informants and facility respondents perceiving that the new vaccine introductions had increased coverage of other vaccines, the routine data showed no change. Positive effects perceived included enhanced credibility of the immunisation programme and strengthened health workers' skills through training. Negative effects reported included an increase in workload and stock outs of the new vaccine creating a perception in the community that all vaccines were out of stock in a facility. Most effects were found within the vaccination programme; very few were reported on the broader health system. Effects were primarily reported to be temporary, around the time of introduction only.
Conclusion: Although the new vaccine introductions were viewed as intrinsically positive, on the whole there was no evidence that they had any major impact, positive or negative, on the broader health system.

1. Introduction

The pace of new vaccine introductions in low- and middle-income countries has been accelerating in the past decade and will continue [1]. This has led to increased attention on their broader impact, with the possibility that they may either stress or strengthen health systems in these countries. In 2010, the World

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Table 1
Details of the vaccine introductions studied: data collection period, introduction process and other contextual information.

Country	Vaccine studied	Date of introduction	Data collection period	Vaccine introduction process
Cameroon	PCV13	July 2011	May–June 2012	GAVI funded Planned for PCV7 in 2010 Switched to PCV13 when it became available, but supply issues delayed its introduction
Ethiopia	PCV10	November 2011	December 2012–January 2013	GAVI funded Catch up for <1 year olds
Guatemala	Rotavirus	February 2010	July 2011	Government funded Only limited introduction preparations; no introduction plan prepared Initially introduced Rotateq (two doses), then switched to Rotarix (three doses), then back to Rotateq Rotateq not purchased through PAHO revolving fund No national social mobilisation
Kenya	PCV10	February 2011	July–August 2011 and March–April 2012	GAVI funded. First sub-Saharan African GAVI country to introduce PCV Catch up for <1 year olds
Mali	Men A	September 2010–December 2011	July–August 2011 and January 2012	GAVI funded Introduction over three phases 10 days campaign, targeting 1–29 year olds Key role of WHO MSF implemented in a few districts
Mali	PCV13	March–December 2011	March–June 2011 and January 2012	GAVI funded Nationwide introduction phased over 10+ months
Rwanda	HPV	April 2011	August 2012	3 years donation from Merck First African country to introduce HPV Vaccination through school-based 2-day campaign for girls in 6th year of primary school. Some catch up in other grades during second and third year of campaigns. For girls not at school, 12 year olds were targeted at the nearest health centres Campaign ran three times per year

Health Organization (WHO) set up an ad-hoc working group to explore the issue for their Strategic Advisory Group of Experts on Immunisation [1]. Members of the team for the present study participated in this group and our preliminary results informed the group's findings and recommendations [2].

There is a lack of research focusing on the impact of new vaccine introductions on countries' expanded programme of immunisation (EPI) or health systems as a whole, particularly in low-income countries [3,4]. Previous research has typically focused either on the impact of vaccination campaigns on the routine immunisation service [5–8], or on the impact of new vaccine introductions on specific elements of the health system, such as cold chain [9], logistics and supply [10,11] or coverage [12].

The EPI is traditionally a relatively vertical programme, although routine immunisation is arguably more integrated than vaccination campaigns. Research on the health system impact of other vertical health programmes, including vaccination campaigns, have identified both positive and negative effects [6,13–16]. It has also been noted that these impacts varied depending on the strength of the health system [6,15].

This study aimed to explore impact of new vaccine introductions on immunisation programmes and the broader health system. It did not aim to estimate the costs of new vaccine introductions as this would require a different type of methodology and has been the focus of another multi-country research project.

2. Methods

We conducted mixed-method case studies of seven vaccine introductions in six low- and middle-income countries (see Table 1 for details). The study team comprised staff from The London School of Hygiene and Tropical Medicine (LSHTM), as well as at least one collaborator per case study country. Data collection was conducted by both the country collaborators and LSHTM staff.

2.1. Case studies sampling frame

Countries were selected to include a range of vaccines, presentations, delivery strategies and financing mechanisms. Countries were eligible for inclusion if they planned to introduce a new vaccine in 2010 or 2011, in order for this introduction to be sufficiently recent at the time of data collection. Five of the seven vaccine introductions were funded by the GAVI Alliance; rotavirus in Guatemala and human papilloma virus (HPV) in Rwanda were the exceptions. In Mali and Rwanda, Meningitis A (Men A) and HPV vaccines were introduced respectively using a campaign-based approach. In Mali, the introduction was through a mass catch-up campaign organised in three separate phases and in Rwanda through a school-based delivery model that was part of the national immunisation schedule. In the remaining countries the new vaccines, pneumococcal vaccine (PCV) and rotavirus, were introduced into the routine, infant immunisation programme.

2.2. Within-country sampling

Within countries, two to four regions were selected based on their vaccination coverage (high, average and low compared to national figures). Two to three districts were selected purposively within each region, representing different vaccination coverage rates as well as both urban and rural areas.

One to five health facilities were selected per district, based on an increasing distance from the main urban centre and to include a range of provider types (Table 2).

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Table 2
Number of regions, districts and facilities included in study, per country.

Country	Regions	Total districts (Districts per region)	Total facilities (Facilities per district)
Cameroon	3	9 (3)	28 (3–4)
Ethiopia	4	10 (1–3)	26 (1–3)
Guatemala	3	9 (3)	27 (3)
Kenya	3	9 (3)	43 (4–5)
Mali (Men A)	2	6 (3)	18 (3)
Mali (PCV)	3	9 (3)	27 (3)
Rwanda	3	9 (3)	27 (3)

2.3. Data collection

Three methods of data collection were used:

1. Semi-structured interviews with key informants selected at national, regional and district levels.
2. Structured questionnaire with health facility staff.
3. Collection of routine vaccination and antenatal care (ANC) service use data.

The qualitative data collection and analysis were framed by an adapted version of the WHO health system building blocks (see Table 3) [17].

Semi-structured interviews at the national level were conducted with key informants from the Ministry of Health and stakeholders from other relevant organisations (e.g. WHO, UNICEF, Inter-agency Coordinating Committee members and, in Rwanda, teachers). Regional- and district-level health service managers and staff specialised in immunisation or logistics management were also interviewed. The interviews included questions on the health system building block components detailed in Table 3; where interviewees' roles were more specialised, questions focused on their areas of expertise. Interviews were recorded when permitted and possible. All those recorded were transcribed and, when necessary, translated. Notes were made of interviews not recorded.

Table 3
Study analysis framework.

Health system building block	Vaccination-specific components
Service delivery	☐ Access and utilisation ☐ Delivery modalities ☐ Demand and acceptance
Health workforce	☐ Availability and distribution of staff ☐ Training and capacity of staff ☐ Remuneration and satisfaction ☐ Performance and supervision
Health information system	☐ Routine data collection and reporting ☐ Disease surveillance
Medical products, vaccines and technologies	☐ Forecasting and procurement of vaccines and injection supplies ☐ Stock management ☐ Cold chain management and waste disposal
Financing and sustainability	☐ Affordability ☐ Domestic financing ☐ External financing
Leadership/governance	☐ Regulatory policy ☐ Political commitment ☐ Organisation, structure, reform, negotiation, stewardship

A researcher-administered questionnaire was completed with one staff member in each facility. Questions were adapted from the WHO's post-introduction evaluation (PIE) tool and were structured around the study framework (Table 3) [18].

Data were gathered on coverage of the new vaccine and the diphtheria, tetanus, pertussis (DTP) as well as ANC service use, from routine service use records held in facilities and/or districts. Monthly data were collected for 1 year before and after the new vaccine was introduced in that facility/district (only 5 and 10 months afterwards in Kenya and Cameroon, respectively, due to the timing of data collection). In Rwanda and Mali (for Men A), data were collected 1 month before, during and after the campaign.

2.4. Analysis

Thematic content analysis was used to explore the interview data within Open Code software [19]. Two investigators led the cross-country analysis of the transcripts and findings were checked with other members of the LSHTM study team and the in-country researchers. The study's framework was used to structure this analysis (see Table 3). Questionnaire responses were cleaned and recorded to allow comparison across countries, where necessary and possible. They were then analysed using descriptive statistics in SPSS software. Routine data were plotted over time and if a small change in trend was visible, a segmented regression analysis was conducted to formally test its statistical significance [20].

2.5. Ethics

Ethical approval was gained from the London School of Hygiene and Tropical Medicine and from the study countries. The study was verbally described to participants, an information sheet was provided and signed consent gained from all prior to commencing data collection.

3. Results

3.1. Data collected

261 semi-structured interviews were conducted and 196 health facility questionnaires were completed (see Table 4). 245 interviews were recorded (94%) and 65 interviews were translated from Spanish, Amharic and Kinyarwanda into English.

3.2. Overall impact

The new vaccines generally seemed to integrate well into existing health systems. The introductions were considered to have had no impact on many of the elements within the building blocks framework (see Table 5 for summary of findings). Of those effects that were identified, most were within the vaccination programme; very few effects on the broader health system were reported. Some effects (e.g. increased staff workload) were reported to be temporary, at the time of introduction only. Given space limitations, only key findings are discussed below.

3.3. No effect

3.3.1. Access and utilisation

Despite many key informants and facility respondents perceiving that the new vaccine introductions had increased coverage of other vaccines, especially in Kenya, Cameroon and Ethiopia, the routine data collected in all countries did not support these claims (see Fig. 1). The only exception was in the case of Mali (PCV), where uptake of the first pentavalent dose increased by about 40% (Fig. 1), although this effect was not sustained over time. However it should

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Table 4
Data collected in each case study.

Country	National interviewees	Regional interviewees	District interviewees	Total number of interviewees	Number recorded	Number translated	Facility questionnaires
Cameroon	10	14	23	**47**	45	None. Interviews and analysis conducted by French and English speakers	28
Ethiopia	8	4	11	**23**	21	13 translated from Amharic, 10 conducted in English	26
Guatemala	11	15	16	**42**	42	All translated from Spanish	27
Kenya	14	11	26	**51**	49	None. All interviews conducted in English	43
Mali (Men A)	19	3	9	**31**	29	None. Interviews and analysis conducted by French speakers	18
Mali (PCV)	1*	8	28	**37**	31	None. Interview and analysis conducted by French speakers	27
Rwanda	12	n/a	11 (+7 school employees)	**30**	28	10 translated from Kinyarwanda into English	27
Total				**261**	**245 (94%)**	**65**	**196**

* 15 national interviews in Mali discussed both Men A and PCV13 introduction – these have been included under 'Mali Men A'.

also be noted that the analysis in Mali (PCV) was based on data from only 13 of the 27 included facilities, due to incomplete data being available in the remaining 14 facilities.

The high demand for new vaccines may have encouraged those who had previously defaulted on existing routine vaccinations. This created an opportunity to check the vaccine status of those attending and, when necessary, administer missed doses. Although study participants reported isolated efforts to use the new vaccine to trace defaulters in this manner, no country demonstrated a systemic approach to this.

No impact of the introduction on ANC service use was observed from routine data before and after the introductions.

3.4. Cold chain

Study participants generally felt that the new vaccine introductions had not affected cold chain capacity for other vaccines or products, for a number of reasons. Cold chain assessments had been conducted as part of the planning process (for GAVI countries, it is required as part of the application process). In some cases, such as in Rwanda, no expansion was deemed necessary. In other countries national-level interviewees reported that there had been an expansion or modernisation of the cold chain in preparation for the introduction, although this was generally at the national and sub-national levels, rather than in facilities.

There was a discrepancy between some national- and facility-level responses, with the former reporting cold chain expansion whilst the latter reported none. It is not clear whether this discrepancy was because expected expansions had not occurred, or whether facility staff had not realised that new equipment received (sometimes up to a year earlier) was for a particular vaccine introduction.

In four countries, the presentation of other vaccines had changed (pentavalent in Cameroon, Kenya and Mali, and PCV in Rwanda), which reduced their cold chain requirement, making capacity available for the new vaccine. Finally, some districts and a minority of facilities reported using adaptive strategies, such as more frequent vaccine deliveries, in order to manage their cold chain space.

> "There is a problem with the cold chain because the volume [of vaccines] is bigger and districts are struggling with the cold chain. . . there is no space. They [the health centres] have to take small quantities; we send them the remainder when there is an opportunity. This creates a risk of stock outs. . ."
>
> C_05, regional-level interviewee, Cameroon

Guatemala was an exception in that no assessment was conducted before the introduction and there was no nationally-organised cold chain expansion. Some equipment was reported to have been procured at sub-national levels after the introduction.

3.5. Regulatory policy

Interviewees in most countries reported no effect on regulatory policies, with some exceptions. In Kenya, WHO worked to strengthen the country's Pharmacy and Poisons Board in order to register the new vaccine. It was felt that this would be beneficial for future vaccines. In Mali, the national regulatory process was bypassed for both Men A and PCV vaccines. In doing so, some interviewees argued that this weakened national ownership and domestic regulatory processes.

3.6. Organisation, structure, reform, negotiation and stewardship: Inter-agency Coordinating Committees (ICCs)

In most countries the new vaccines were not thought to have affected the functioning of their ICCs. However, in Mali (for Men A) and in Rwanda, membership of the committees was extended to additional stakeholders. In Ethiopia some interviewees felt that the ICC had been strengthened by the introduction, particularly because of highly active thematic sub-committees.

3.7. Demand/acceptance

Vaccination is, in general, well accepted and this was the case for the new vaccines too, with high acceptance and demand reported. Only a minority of facilities reported that they had experienced any resistance from the community regarding the new vaccine – this was most common in Rwanda for the HPV vaccine, or because of a fear of the effect of receiving two vaccinations at once (e.g. in Ethiopia, where PCV and pentavalent were given at the same time). Study participants did not feel that the new vaccines had affected the acceptance of other vaccines, perhaps due to the fact that they were already well accepted.

4. Positive effects

New vaccine introductions were seen as intrinsically positive, to such an extent that some study participants felt that their addition per se strengthened the health system in a general sense.

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Table 5
Impact of new vaccine introductions by health system building block components.

Health system building block	Vaccination-specific components	No impact on:	Positive impact on:	Negative impact on:
Service delivery	Access and utilisation	Other vaccines' coverage rates Health service use		
	Delivery modalities	Delivery modalities Co-delivery of interventions alongside vaccination (except Rwanda, positive impact)		
	Demand and acceptance	Acceptance of other vaccines	Trust and credibility of EPI enhanced	
Health workforce	Availability and distribution of staff	Staffing numbers or distribution (except for campaign-based introductions)		Workload increased in the short term
	Training and capacity of staff		Skills strengthened through training	
	Remuneration and satisfaction	Remuneration (except for campaign-based introductions)	Staff morale boosted	
	Performance and supervision	Supervision		
Health information system	Routine data collection and reporting	Information systems		
	Surveillance	Disease surveillance	Awareness of adverse events following immunisation (AEFIs) increased (although no effect on reporting) Strengthening of AEFI surveillance systems (Ethiopia, Mali)	
Medical products, vaccines and technologies	Forecasting and procurement of vaccines and injection supplies	Forecasting/procurement		
	Stock management	Stock management Wastage rates		Stock outs of new vaccine – creating a perception that all vaccines were out of stock in the facility
	Cold chain management and waste disposal	Cold chain (at facility level) Waste management		
Financing and sustainability	Affordability	Operational costs (although lack of monitoring)	Outbreak costs reduced (Mali Men A)	Reduced revenues at facility (Mali Men A)
	Domestic financing		Domestic financing increased	Sustainability concerns
	External financing		External financing increased	
Leadership/governance	Regulatory policy	Regulatory policy (all countries except in Mali and Kenya)	Pharmacy and Poisons Board (in Kenya only)	Regulatory policy (in Mali only)
	Political commitment		Reinforced EPI support	
	Organisation, structure, reform, negotiation, stewardship	Planning Inter-agency Coordinating Committees (except for Ethiopia and campaign-based introductions)	Collaboration enhanced (at national level)	

> "I think any new antigen reinforces routine vaccination programme because mothers know their children are better protected."
>
> M016, national-level interviewee, Mali (PCV)

Respondents felt that the new vaccines would lead to a reduction in disease and would increase the public's trust in the health system.

4.1. Training

Staff training in preparation for the introductions was viewed overwhelmingly positively. Some participants explained that it acted as a refresher, allowing staff to update their vaccination skills, e.g. cold chain management, as well as informing them about the new vaccine.

4.2. Disease surveillance and AEFIs

There was generally no impact on disease surveillance systems overall. However in some countries positive effects were reported, namely Cameroon, Mali and Kenya, where surveillance staff capacity had reportedly been enhanced. In addition, in Mali (Men A) case-based surveillance of meningitis was introduced. This lack of impact may be because the development and strengthening of surveillance systems was part of broader developments within the health system and as such, were not tied specifically to individual vaccine introductions.

Study participants felt that the effect of the new vaccine introductions on adverse events following immunisation (AEFI) reporting was positive, though limited. In Ethiopia and Mali, the AEFI surveillance systems had been strengthened, with training and specific communication for health workers on how to identify

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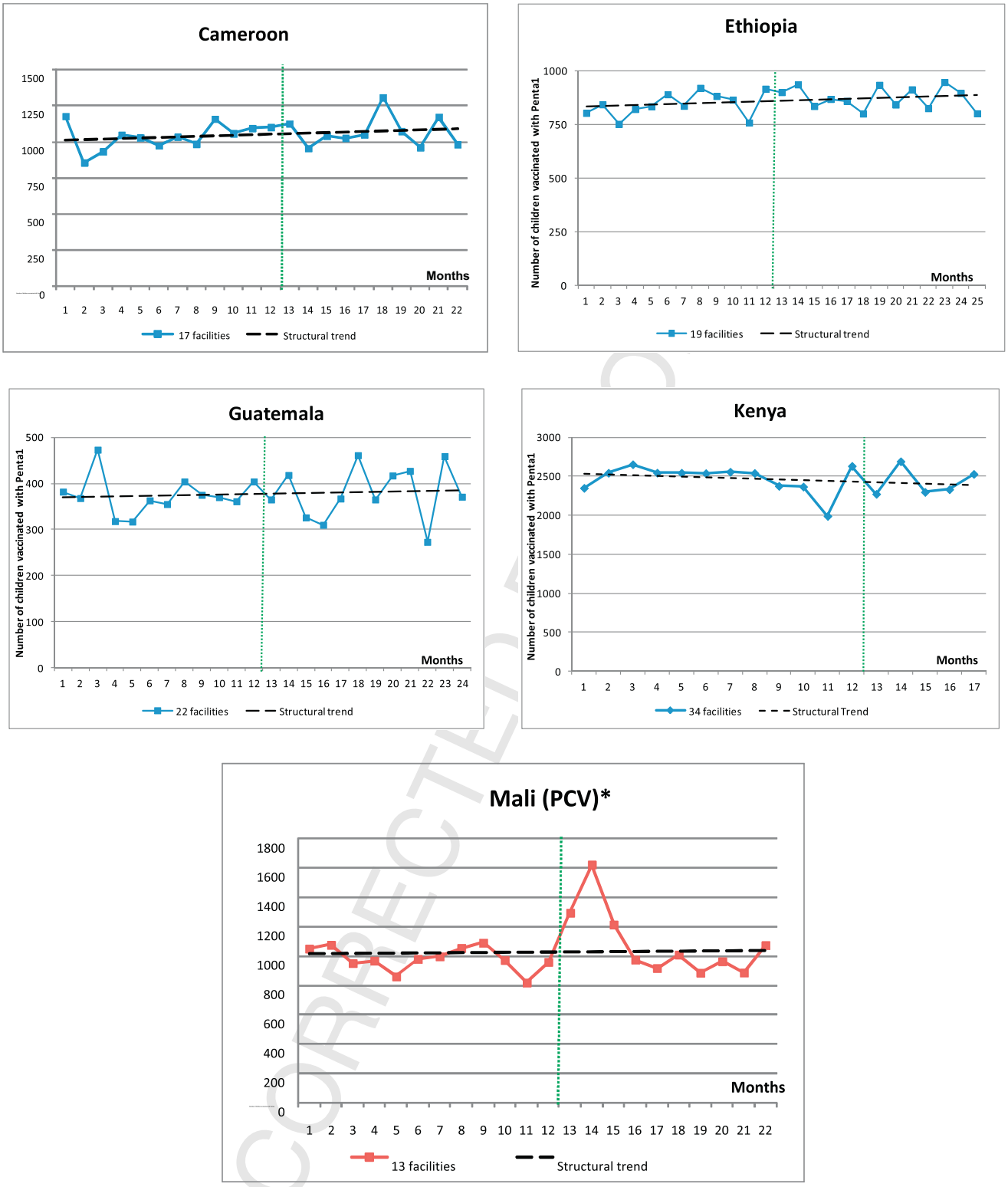

Fig. 1. Number of children vaccinated with Pentavalent 1 per month, before and after the introduction of a new routine vaccine*.
*Only countries introducing the new vaccine into their routine immunisation schedule i.e. Cameroon, Ethiopia, Guatemala, Kenya. Mali (PCV).
*Because of the phased introduction of the PCV13 in Mali, we could only collect data for 10 months post introduction in 13 health facilities.

and respond to AEFIs for the new vaccine and the strengthening of national and regional committees for surveillance of AEFIs. In several countries (particularly Kenya, Ethiopia and Mali for Men A) a lot of attention was placed on creating awareness of potential AEFIs. These countries introduced vaccines with particular safety concerns; Kenya was the first GAVI-eligible country to introduce the preservative-free PCV vaccine, shortly followed by Ethiopia, whilst Mali introduced a completely new Men A vaccine [21].

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However despite overwhelming reports of enhanced awareness of AEFIs, this did not lead to a change in the number of AEFIs reported by health facilities, for any vaccine.

4.3. Financing

The impact of the new vaccines on domestic and external financing was viewed positively. Domestic funding for vaccines was increased, albeit only for GAVI co-financing in most cases; operational funds were generally reported to have remained unchanged. Some interviewees believed that GAVI co-financing encouraged a sense of national ownership although concerns were also expressed regarding financial sustainability. It was also felt that the new vaccines provided access to additional external financing; some key informants explained that the GAVI funding spurred others to offer additional support (e.g. for cold chain expansion).

4.4. Organisation, structure, reform, negotiation and stewardship: collaboration

There were only changes in collaborations in a few specific cases, where the new vaccine introduction led to new or strengthened collaborations. For example, in Rwanda new collaborative links were made with the Ministry of Education due to the school-based delivery strategy. In Kenya, multi-sector working had been established for previous vaccine introductions and had continued for this latest one, but there were also reports of new or improved links with the departments of health promotion and HIV. In Mali the preparatory work for Men A increased collaboration between the agency for social mobilisation, the Ministry of Health and the National Institute for Infectious Diseases.

5. Negative effects

There were few negative impacts reported and these were often only felt to occur in the short term, immediately after the introduction.

5.1. Availability and distribution of staff: workload

The majority of health facility respondents (61%) reported that workload had increased at the time of, or just after, the new vaccine introduction. The effect on workload seemed to vary between countries; a perceived increase in workload was most common in Kenya than Guatemala or Ethiopia. Some explained that the increase was only temporary, perhaps caused by catch-up strategies, returning to normal levels after a few months.

5.2. Stock management: stock outs

Stock outs of the new vaccine were experienced in all the 'routine introduction' case studies (i.e. where the new vaccine was integrated into routine infant immunisation services, as opposed to case studies where the new vaccine was delivered via campaigns), although they were more common in some than others (e.g. in Kenya, 51% of facilities reported stock outs compared to 8% in Ethiopia). In many cases stock outs were reported to be particularly notable in the first few months after introductions, when either demand exceeded expectations or a catch-up strategy had not been incorporated into forecasting predictions.

Stock outs of other vaccines were also reported, but were rarely associated with the new vaccine because they had occurred before the introduction as well. Stock outs had broader implications than just access to the new vaccine; interviewees and facility staff explained that when one vaccine was out of stock, the public perceived there to be a generic vaccine stock out and so stayed away from immunisation services even if the specific vaccine that they required was available.

> "So when it [the new PCV vaccine] is out of stock, it will affect the other vaccines which are available because the common person will just say, 'The vaccine is not there.' Then even the other [person] who was supposed to get the other [vaccine] which is available will not come."
>
> K022, regional-level interviewee, Kenya

5.3. Differences between routine EPI and campaign-based introductions

Unlike the other case studies, no stock-outs of the new vaccines were reported in either country. This may be because their delivery and logistics systems were separate from routine services, or because they were required only for a limited period of time.

In Rwanda, since the vaccine brought the immunisation service to a completely new target population and delivery mode (school-based), the opportunity was taken to co-deliver various interventions alongside the HPV vaccine, such as health promotion sessions and de-worming treatment.

In Mali it was reported that there had been no more Men A outbreaks since the new vaccine introduction. This meant that expensive reactive campaigns were avoided. However, the campaign disrupted routine services, which had the perceived knock-on effect of reducing facilities' revenues from those services. Although the new vaccine campaigns ran for a limited time only, in the Malian context where there are frequent short-term campaigns, these routine service interruptions could add up to considerable regular disruption [22].

Overall, both benefits and drawbacks of campaign-delivered introductions seemed to be limited to the duration of the campaigns.

6. Discussion

As far as the authors are aware, this is the first study to focus specifically on the impact of new vaccine introductions on the broader health system in low- and middle-income countries. Our study found that the new vaccines generally integrated well and as such, had little or no impact on most aspects of the EPI and even less on the broader health system. Effects outside of EPI were minimal or limited to a few cases where a deliberate effort was made to combine activities.

Our findings showed that there were limited inter-departmental collaborations during introduction planning and this may explain why the impacts were more narrowly circumscribed to immunisation.

Perhaps the most surprising findings were the lack of impact on coverage rates for other vaccines (apart from a transient effect for PCV13 in Mali) and the discord between this finding (from the routine data) and the perceived increase reported by interviewees and facility respondents. Some studies have reported a perceived increase in health service use following the introduction of services or new vaccines [3,16], however, others found no change [6,12]. Our results suggest that findings based on *perceptions* of increased service use should be treated with caution.

The finding that the introduction of an additional vaccine did not have many negative impacts, particularly for components such as the cold chain capacity (except in Guatemala, where planning was minimal), is a testament to the value of introduction preparations. It has been shown elsewhere that vial size affects supply chain requirements and vaccine availability [23] and there is recognition of the general need for additional cold chain for new vaccine introductions [11,24,25]. It should not be forgotten that health systems

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are dynamic; fortuitous changes in the presentation of other vaccines as well as other concurrent initiatives (e.g. increasing staffing) as reported in this study, cannot be relied upon for future vaccine introductions.

6.1. Limitations

This study was conducted in seven countries only and focused on five new vaccines. The effect of introductions will vary depending on the nature of the new vaccine and its delivery, the degree of preparation undertaken and the context of the EPI and broader health system [4]. These findings may therefore not be generalisable to all introductions in all settings. Nevertheless, they highlight key issues that may be relevant to those introducing new vaccines in low- and middle-income countries.

The inherently positive perception of new vaccines may have made it difficult for respondents to report negative. The vertical nature of EPI meant that many interviewees found it difficult to respond to questions about the broader health system; conversely those outside of EPI often had little knowledge about new vaccine introductions. In some case studies the planned introduction was delayed, resulting in fewer months of post-introduction data being available to the study team. Finally, in some cases, particularly in Mali (PCV), routine health service use data were not available in all facilities.

7. Conclusion

Although the new vaccine introductions studied were viewed as intrinsically positive, there was no evidence that they had any major impact, positive or negative, on the broader health system.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.vaccine.2014.09.031.

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